REMARKS

Applicants note the Examiner's withdrawal of the finality of the rejections stated in the Office Action mailed July 21, 2005, in view of applicants' Brief on Appeal mailed February 17, 2006. Applicants will address each of the newly-stated grounds of rejection in detail below.

Response to the Non-statutory Double Patenting Rejection

Applicants note the provisional rejection of claims 1-4, 8, 9, 12-15, and 31 on non-statutory double patenting grounds over: (1) co-pending application Serial No. 10/845,936; (2) co-pending application Serial No. 10/845,775; and (3) co-pending application Serial No. 10/939,036. Applicants further note that application Serial No. 10/845,936 has been abandoned in favor of a continuation application, Serial No. 11/351,712. To obviate these provisional rejections, applicants are filing with this paper terminal disclaimers pursuant to 37 CFR §1.321. Applicants previously amended the specification to provide a statement of a Joint Research Agreement between Genencor International, Inc. and the Dow Corning Corporation. All of these applications are owned either singly or jointly by the two companies.

Objection to Claims 1 and 3

Applicants note the Examiner's objection to the language "amino acid sequence" in claims 1 and 3. Claims 1 and 3 have now been amended to recite that the variables T and T' comprise either an amino acid or an amino acid sequence of from about 1 to about 60 amino acids.

Rejection of Claims 1-4, 8, 9, 12-15, and 31 under 37 CFR §112, ¶1

In the Office Action, the Examiner rejected claims 1-4, 8, 9, 12-15, and 31 under 35 USC §112, ¶1 as failing to comply with the written description requirement. Applicants understand this ground of rejection is not based on a lack of corresponding language in the specification that is as broad as the claim language. Rather, applicants understand the rejection to be based on the Examiner's assertion that an insufficient number of representative species of repeat sequence protein polymers have been described such that one skilled in the art would recognize that the

applicants had possession of the presently claimed invention ("the specification is void of a sufficient number of examples to describe the infinite number of peptide compositions within the genus with the requisite activity" (page 7)). While applicants will concede that a large number of compositions are encompassed by the present claims, the claims are certainly not "infinite" in scope as alleged. Rather, the claims define a class of repeat sequence protein polymers (RSPPs) having a well-defined chemical structure as explicitly recited in all claims.

Applicants further note that this ground of rejection is essentially a repeat of the rejection stated in the Office Action mailed January 25, 2005, which rejection was subsequently withdrawn by the Examiner in the Office Action mailed July 21, 2005 ("Applicant's arguments filed April 27, 2005, with respect to the rejection ... of claim 1 under 35 USC § 112 1st paragraph, have been fully considered and are persuasive, upon Applicants amendment to the claims.") In the most recent Office Action, the Examiner has provided no explanation why claims that were held to be in compliance with §112, ¶1 are now held not to be.

Applicants can only essentially reiterate the reasons that were provided to the Examiner previously and which were found, at the time, to have been "persuasive." Specifically, the Examiner again conducts the same five factor analysis (Office Action, pages 5-7) as previously conducted. The Examiner again acknowledges that written description exists for SEQ ID NO: 19, SELP-47-K, and the compounds identified in the specification tables and/or examples (Office Action, page 7), but asserts that such specific compositions and examples are insufficient. For the reasons set forth in detail below, this rejection is again traversed, applicants arguments in their previous Amendment mailed April 25, 2005, are incorporated by reference herein, and reconsideration is again respectfully requested.

First, with respect to the level of skill in this art, the Examiner concedes that the synthesis of peptides "is well known in the art." Again, however, the Examiner makes the unsupported assertion that the scope of the claims is "infinite" and the "desired characteristics" of the compositions are "undefined or unable to be correlated with a particular structure." Applicants controvert that the "desired characteristics" of the claimed compositions are "undefined." The specification provides substantial description of both the desired characteristics and benefits of the compositions as well as the surfaces (skin, hair, nails, and oral) that the characteristics and

benefits are directed to. See, page 3, paragraph [0010] and pages 4, paragraph [0015], for example.

Regarding the Examiner's objections to applicants' definition of the structure of the claimed RSPPs, applicants have amended claims 1 and 3 to remove the word "about" from the recitation of the number of amino acid groups. Applicants certainly strongly disagree with the Examiner's unreasonable interpretation that "about 3" encompasses a single amino acid. And, applicants have canceled claim 2 so that the Examiner will no longer be confused about naturally-occurring compositions having repeat sequences. The claims are directed to synthetic RSPPs having the structure set forth in the claims.

Applicants also strongly disagree with the Examiner's "inference" that the recitation of the A, A', and A" repeating sequence units in the claims *requires* that the claimed compositions have at least 90 repeating A, A', and A" units. As previously explained in detail, and as clearly set forth in the claims, the variables x, x', and x" are recited to be either zero or an integer of at least 1, where not all of x, x', and x" can be zero, and "where each integer varies to provide for at least 30 amino acids in the A, A', and A" individual repeating sequence units."

With respect to the Examiner's criticism of the description that is provided on how to make the claimed compositions, the processes for manufacturing any of the claimed RSPPs from the disclosed proteins are known in the art, and characteristics of the proteins themselves are known in the art. Specific selection criteria with respect to the RSPP protein components would be apparent to a person of ordinary skill in the art once the desired characteristics have been determined. The specification clearly teaches that selection of the proteins which form the RSPPs are based on what characteristics are desired in a particular personal care composition embodiment. For example, compositions comprising SELP47K contemplate applications where the combined attributes of durability and elasticity are desired. A person of ordinary skill in the formulation arts, however, will readily recognize from the materials provided in the written description how to select and how to make the claimed RSPPs.

According to case law governing the application of the written description requirement, a sufficient description of a genus may be achieved in several ways. One of them is by disclosure of a "representative number" of species as noted by the Examiner. But another is "by recitation of structural features common to the members of the genus, which features constitute a

substantial portion of the genus." Applicants respectfully point out that this requirement is notably not a conjunctive, but an either/or. *Regents of the University of California v. Eli Lilly & Company*, 119 F.3d 1559, 1569, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This case law is cited approvingly in the USPTO's "Revised Interim Written Description Guidelines," Example 7.

For all of these reasons, applicants submit that the language of the amended claims is fully described by the present specification in accordance with the requirements of 35 USC §112, first paragraph. Reconsideration and withdrawal (again) of this ground of rejection are respectfully requested.

Rejection of Claims 1-4, 8, 9, 12-15, and 31 under 37 CFR §112, ¶2

In the Office Action, the Examiner rejected claims 1-4, 8, 9, 12-15, and 31 under 35 USC §112, ¶2 as being indefinite. Each of the Examiner's objections will be discussed in turn.

Initially, the Examiner opined that claims 1 and 3 were indefinite in their recitation of the minimum number of amino acids in the recited A, A', and A" individual repeat sequence units. While applicants believe that the claims are clear, and the minimum number of A, A', and A" individual repeat sequence units is 30, applicants have amended claims 1 and 3 to clarify this. Reduced to their simplest forms, where only one of x, x', or x" is not zero, the claims are clear in requiring that there be a minimum of at least 30 amino acids in whichever A, A', or A" individual repeat sequence unit has an x, x', or x" value not equal to zero.

The Examiner also objects to the use of the term "effective amount" even after conceding that the term is defined in the specification (Office Action, page 8). As defined in the specification, an effective amount is an amount which provides a benefit to the surface to which the personal care composition is provided. As the Examiner must concede, such amounts will vary depending on the desired benefit and the surface to which the composition is applied. However, applicants have now amended claim 1 to specify a range of amounts of repeat sequence protein polymer in the composition. The recited weight percentages are both clear and definite.

Claims 1 and 3 have been amended to address the Examiner's concerns regarding the use of the term "about 3 to about 30 amino acids." Claim 2 has been canceled, mooting the Examiner's stated objections with respect to that claim.

For all of the above reasons, applicants submit that the claims as amended are clear, definite, and in compliance with §112, ¶2.

Rejection of Claims 1-4, 8, 9, 12-14, and 31 under 37 CFR §102(b) to Wolfinbarger

In the Office Action, the Examiner rejected claims 1-4, 8, 9, 12-14, and 31 under 35 USC §102(b) as anticipated by Wolfinbarger. This was the sole stated ground of rejection in the final rejection mailed July 21, 2005. Further, the Examiner has conceded at page 2 of the present Office Action that he was in error to reject these claims by applying "the structure of a Type I collagen to a Type V collagen."

The present rejection appears to be based on the Examiner's assertion that "any collagen meets the limitations of these claims regardless of the source." Prefacing that statement, the Examiner discussed portions of applicants' specification that are directed to naturally occurring compounds that include repeating amino acid sequence units. Such naturally-occurring compositions include collagen-like proteins (specification at page 4, paragraph [0019]). The Examiner has thus rejected the *claims* based on general statements found in the *specification*. Implicit in this rejection is the Examiner's conclusion that the claims as presented read on naturally-occurring collagens such as the Type V telopeptide described by Wolfinbarger. Applicants submit that the claims do not.

Independent claim 1, and the claims which depend therefrom, are directed to specific *synthetic* RSPPs. The claimed RSPPs are believed to bear little or no structural relationship to the Type V telopeptides of Wolfinbarger. Wolfinbarger is silent concerning the chemical structure of his Type V telopeptides, and the Examiner has not produced any evidence of that structure. The Examiner opines that "Applicant has not provided any evidence to prove type V telopeptide collagen is not the same as what is instantly claimed ...." (Office Action, page 10). The Examiner has seriously misplaced the burden of proof here. It is the Patent Office's burden to establish that the prior art anticipates a claim. 35 USC §102 ("A person shall be entitled to a patent unless..."). To do so, the Examiner must show that the applied reference meets each and

every limitation of the claims and is enabled. See, *In re Sasse*, 207 USPQ 107 (CCPA 1980). The Examiner previously relied on Voet to establish that the collagen of Wolfinbarger anticipated the claimed subject matter. The Examiner now concedes that Voet cannot be used in that manner. Thus, the Examiner is left with a reference that is **silent** concerning the chemical structure of the Type V telopeptide. The Examiner has not carried his burden of proof here.

And, the Examiner's citations to *In re Best*, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980) are inapposite. Only where the PTO has cited prior art which is identical to or substantially identical to the claimed subject matter does the burden shift to an applicant to rebut a prima facie case. Wolfinbarger's silence does not constitute a prima facie case that Wolfinbarger teaches to one skilled in this art each and every limitation recited in the claims. The rejection is not supported by evidence and should be withdrawn.

Rejection of Claims 1-4, 8, 9, and 31 under 37 CFR §102(b) by Crissman

In the Office Action, the Examiner rejected claims 1-4, 8, 9, and 31 under 35 USC §102(b) as anticipated by Crissman. Crissman describes silk elastin like proteins (termed "Prolastins") used in compositions containing a genetically-engineered mitotoxin (termed "Pantarin") which were injected subcutaneously and intradermally into guinea pigs. The Examiner asserted that the Crissman composition constituted a "personal care composition" because it provided a "benefit, such as beautifying or treating via reduction of tumors." (Office Action, page 12).

Applicants disagree that the composition of Crissman would reasonably be understood by anyone to be a "personal care composition" as that term has been used in the art and defined by applicants. Applicants have amended claim 1 to make it clear that the claimed composition is a personal care composition adapted for topical application to the skin, hair, nails, or oral cavity to provide at least one benefit to those surfaces. Crissman does not teach or suggest a topically applied composition. Crissman teaches injecting the composition beneath the skin. Nor is Crissman a personal care composition. Injection of a mitotoxin to inhibit the growth of tumors below the surface of the skin of a guinea pig provides no benefit to the surface of the skin as claimed by applicants.

Further, applicants have also amended claim 1 to recite a range of weight percentage amounts of the RSPP in the composition taken from now canceled dependent claim 12. Applicants note that the Examiner did not reject claim 12 over Crissman. Accordingly, for all of the above reasons, applicants submit that the claims as amended are patentable over Crissman.

Rejection of Claims 1-4, 8, 9, and 31 under 37 CFR §102(b) by Cappello

In the Office Action, the Examiner rejected claims 1-4, 8, 9, and 31 under 35 USC §102(b) as anticipated by Cappello (WO 95/24478). Cappello (a co-author of the Crissman article above) also teaches certain protein polymers based on repeating amino acid sequences. The Examiner asserts that one of such protein polymers (identified as SELP 5) was made into sponges, soaked in saline solution, and applied to pig dermal wounds. The Examiner asserted that such sponges comprise a "personal care composition" that provides a "wound healing" benefit.

However, the title of Cappello is "Synthetic Proteins as *Implantables*" (emphasis supplied) and the purpose of the fibrous sponges was to be positioned into a "wound bed." The Cappello sponges are not designed to be topically applied. By definition, an open wound bed is not the surface of skin, but rather is the absence of skin from a body.

Further, applicants have also amended claim 1 to recite a range of weight percentage amounts of the RSPP in the composition taken from now canceled dependent claim 12. Applicants note that the Examiner did not reject claim 12 over Cappello. Indeed, the Cappello sponges comprise 100% of the protein polymer. Accordingly, for all of the above reasons, applicants submit that the claims as amended are patentable over Cappello.

Conclusion

For all of the above reasons, applicants submit that claims 1, 3-7, 9, 13-15, and 31, as amended, are patentable over the cited and applied prior art and are in compliance with §112. Early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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